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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,784	03/09/2001	Frederick J. Cassels		1381

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EXAMINER
DEVI SARVAMANGALA J N

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/08/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/801,784	Cassels et al.
Examiner	**Art Unit**
S. Devi, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on 10-31-02 .

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-9* is/are pending in the application.

4a) Of the above, claim(s) *3, 4, 8, and 9* is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *1, 2, and 5-7* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [X] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [X] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [X] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s).
4) [ ] Interview Summary (PTO-413) Paper No(s).
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other:

DETAILED ACTION

Preliminary Amendment

1) Acknowledgment is made of Applicants' preliminary amendment filed 08/23/02 (paper no. 11).

Election

2) Acknowledgment is made of Applicants' election, with traverse, of invention I, claims 1 and 2, filed 10/21/02 (paper no. 13). Applicants' traversal is on the grounds that the compositions containing the peptide and the methods are clearly one invention.

Applicants' argument has been carefully considered, but is not persuasive. It is noted that no specific explanation has been given as to why Applicants regard a product and a method to be one invention. As set forth in the restriction requirement mailed 06/18/02 (paper no. 9), the peptide of invention I belongs to class 530, whereas the method of invention II belongs to class 424, thus requiring separate and burdensome searches that are non-coextensive. Furthermore, as permitted by MPEP 806.05(h), the Office has clearly shown that the product of invention I can be used in a materially different process, such as, a diagnostic assay as a coating antigen. The new claims submitted along with the election filed 10/21/02 are directed to a peptide that is structurally distinct from the peptide claimed in invention I. The restriction requirement mailed 06/18/02 (paper no. 9) is proper for reasons delineated above and is hereby made FINAL.

Status of Claims

3) Claim 1 has been amended via the preliminary amendment filed 08/23/02.

New claims 5-9 have been added via the preliminary amendment filed 08/23/02.

Claims 1-9 are pending.

Claims 3, 4, 8 and 9 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

The elected claims 1, 2 and claims 5-7 which depend from the elected claim are under examination. An Action on the Merits for these claims is issued.

Raw Sequence Listing

4) Acknowledgment is made of Applicants' raw Sequence Listing filed 04/10/02 (paper no. 7), which has been entered on 04/23/02 (paper no. 8).

Priority

5) The instant specification is a continuation of application SN 08/905,140, filed 08/01/1997, now abandoned, which claims priority to the provisional application SN 60/023,076, filed 08/02/1996.

Specification - Informalities

6) The specification is objected to for the following reasons:

(a) The first paragraph of the specification does not accurately reflect the current issued status of the prior application(s) as indicated above under 'Priority'. Amendment to the first paragraph of the specification is requested.

(b) All recitations of "(Seq. #...)" all through the specification, including abstract, claims and the body of the specification, are confusing and/or incorrect. It is suggested that Applicants replace the recitation "Seq. #" with --SEQ ID NO: --.

(c) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R 1.821 through 1.825. For example, page 6 of the specification at lines 13, 18 and 23 and page 3 at line 17 contains sequences of amino acid residues longer than four amino acid residues long, which fail to comply with the sequence rules. Any sequences recited in the instant specification which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825 by identifying the sequences with a SEQ ID NO.

(d) The use of the trademark in the instant specification has been noted. For example, see page 4, lines 24: "Tween 20"; and page 10, line 13: "Coomassie Blue". The recitation should be capitalized wherever they appear and be accompanied by the generic terminology. Each letter of the trademark must be capitalized. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

(e) The recitation "S. pneumonia" in line 16 on page 8 appears to be incorrect. Do

Applicants mean this to be --*S. penumoniae*--?

(f) The recitation "Freunds adjuvant" in claim 7 and in line 14, 19 and 23 on page 6 of the specification are inconsistent with the recitation "Freund's adjuvant" in line 32 on page 10 which is the art-accepted recitation "Freund's adjuvant". See line 6 in column 5 of US patent 5554,372.

Rejection(s) under 35 U.S.C. § 101

7) Claim 1 is rejected under 35 U.S.C. § 101 as being directed to a non-statutory subject matter. The claim encompasses any peptide and therefore reads on products of nature, i.e., naturally occurring peptide. The claim lacks limitations which distinguish the product from those that may exist naturally. Consequently, the claim does not embody patentable subject matter as defined in 35 U.S.C § 101. See MPEP 2105. It is suggested that Applicants use a limitation, such as, --An isolated--, --A purified--, or --An isolated and purified-- in connection with the peptide in connection with the product to reflect the hands of the inventors in the production or creation of the recited product as is supported under 'Materials and Methods'.

Double Patenting Rejection(s)

8) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R 3.73(b).

9) Claims 1, 2 and 5-7 are rejected under the judicially created doctrine of obviousness-type

double patenting as being unpatentable over claims 1, 2 and 6-11 of the US patent 5,914,114 (Cassels) ('114).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., *In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998)*; *In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)*; *In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir, 1985)*.

Claims 1 and 3-5 of the US patent 5,914,114 recite a peptide and a composition comprising the peptide VEKNITVTASVDPTIDLLQADGSALPSAVALTYSPA which contains the instantly recited PSAVALTYSP within the peptide. The claims claiming this peptide differ from the instant claims in that they fail to expressly disclose that a PSAVALTYSP-containing peptide to be 16 to 30 amino acid residues-long. However, the portions of the U.S. patent 5,914,114 that support the description of the peptide in the last paragraph of column 6 teach the preferred peptide of the invention to be at least 30 residues long for use in vaccines. A sequence search performed in the Office confirmed that the prior art peptide contained the instantly recited amino acid sequence PSAVALTYSP. See the attached sequence search report.

Given the express teaching by Cassels ('114) that the preferred peptide of the invention for use in vaccines is at least 30 amino acid residues long, it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce, by routine experimentation, a 30 amino acid-long peptide containing the PSAVALTYSP sequence using art-known fragmentation techniques to produce the peptide of the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of providing the preferred 30 amino acid-long peptide for use in vaccines as taught by Cassels ('114).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

10) Claims 1, 2 and 5-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 2 is confusing and lacks proper antecedence for the recitation "a peptide of claim 1", because there are not more than one peptides claimed in claim 1. For proper antecedence, it is suggested that Applicants change the recitation to --the peptide of claim 1--.

(b) Claim 1 is vague and indefinite in the recitation "peptide of 16 to 30 amino acids from the peptide ..... (Seq. #1)", because it is unclear what does "from the" represent. Is the recitation "from the" equivalent to "isolated from the" or "cleaved from the"?

(c) Claim 1 is vague in the recitation "peptide ... (Seq.#1)" and "the sequence ... Seq. #36" without particularly reciting that the peptide represents an amino acid sequence and the 'sequence' in line 3 of the claim represents an amino acid sequence. In order to distinctly claim the subject matter of the instant invention, it is suggested that Applicants replace the recitation with --peptide of the amino acid sequence ..... (SEQ ID NO: 1)-- and --the amino acid sequence ..... (SEQ ID NO: 36)--.

(d) The recitation "Freunds adjuvant" in claim 7 is incorrect and is inconsistent with the recitation --Freund's adjuvant-- in line 32 on page 10 of the specification.

(e) Claim 5 is vague and confusing in the use of the abbreviation in the claim language: "BSA". It is suggested that the abbreviation be recited as a full terminology at first occurrence, with its abbreviated recitation retained in parentheses.

(f) Claims 5-7, which depend directly or indirectly from claim 1, also stand rejected under 35 U.S.C. § 112, second paragraph, because of the vagueness or indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 103

11) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person. having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

12) Claims 1, 2 and 5-7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cassels (US 5,914,114) (Cassels, '114) or Cassels (WO 96/38171) ('171).

Instant claims are not granted the effective filing date of the provisional application, since it lacks descriptive support for a peptide of "16 to 30 amino acids" from the recited peptide of SEQ ID NO. 1 containing SEQ ID NO: 36.

The reference of Cassels ('114) is applied in this rejection because it qualifies as prior art under subsection (e) of 35 U.S.C § 102 and accordingly is not disqualified under U.S.C 103(a). It is noted that the inventive entity of the applied patent and the instant application is not the same.

Cassels ('114) or ('171) disclosed the peptide VEKNITVTASVDPTIDLLQADGSALPSAVALTYSPA that contains the amino acid sequence, PSAVALTYSP, and a composition comprising the same along with a pharmaceutically acceptable carrier and an adjuvant such as Freund's adjuvant. The peptide is bound to bovine serum albumin. See claims 1 and 3-5; and Examples 3-4 of Cassels ('114 or ('171).

Cassels ('114) does not teach such a peptide that is 16 to 30 amino acids long containing the shorter peptide recited in claim 1.

However, Cassels ('114 or '171) expressly suggested that a such peptide of at least 30 amino acids would be preferred in their invention for use in vaccines (see last paragraph in column 6 of '114 and last paragraph on page 10 of '171).

Therefore, given the express teaching by Cassels ('114 or '171) that the preferred peptide of the invention for use in vaccines is at least 30 amino acid residues long, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce a 30 amino acid-long peptide from the Cassels' ('171 or '114) longer peptide that contains the shorter peptide, PSAVALTYSP, to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention for expected benefit of using the 30 amino acid-long peptide as a vaccine as expressly

suggested by Cassels ('114 or '171).

Claims 1, 2 and 5-7 are *prima facie* obvious over the prior art of record.

Remarks

13) Claims 1, 2 and 5-7 stand rejected.

14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which receives papers 24 hours a day and seven days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

15) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

January, 2003

S. DEVI, PH.D.
PRIMARY EXAMINER